K112754

JUN 15 2012

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	September 13, 2011
Submitter:	GE Healthcare, VersaMed Medical Systems Hasharon Industrial Park Ornat Bldg. p.o. box 5011 kadima, Israel 60920
Primary Contact Person:	Shlomi Deler – Regulatory Affairs Manager GE Healthcare, VersaMed Medical Systems Tel : +972 98915407 Fax: +972 98911499
Secondary Contact Person:	Monica Morrison GE Heathcare, Datex-Ohmeda, Inc. 3030 Ohmeda Drive Madison, WI 53718 Tel: 608-221-1551, Extension 3439 Fax: 608-646-7464 Email: Monica.Morrison@ge.com
US Agent:	Pam Schaub GE Healthcare 9900 w. innovation dr rp2138 wauwatosa, WI 53226 Phone: 414 7212584 ext Fax: 262 9971160 Email: pam.schaub@ge.com
Device: Trade Name:	iVent101
Common/Usual Name:	Portable Ventilator
Classification Names:	868-5895 , Continuous Ventilator
Product Code:	73 CBK, 73 NOU
Predicate Device(s):	iVent101 [cleared under K092135] Trilogy 100 [cleared under K083526]

Device Description: The iVent101 is a compact, portable, microprocessor-controlled ventilator intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation.

A turbine-powered air source and a rechargeable internal battery provide freedom from wall air and power outlets. Internal flow and pressure are read through low/pressure sensors. Clinical data [Tidal Volume, Rate, PIP, FiO2, Peak Flow, Inspiratory Time, I:E Minute Volume] are presented on machine screen.

All the operator actions are performed on the LCD touch-screen on the front panel, allowing rapid control and continuous real-time monitoring of patient ventilation. Alarm settings are fully adjustable.

Optional Waveform and Diagnostic Software package displays pressure and flow waveform data, loops, trends, and logged totals in a full array of time slices and presentation modes.

The iVent101 can use external AC or DC power supply and contains an integrated battery.

The iVent101 is equipped with two configurations, which differs in the patient circuit type that connects to the machine. One configuration is to be used with a standard one limb patient circuit, and the second configuration is to be used with a standard dual limb patient circuit. The two configurations are incorporating the same infrastructure and can be easily replaced by the user.

Intended Use: The iVent101 ventilator [with single or dual limb configuration] is intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. Specifically, the ventilator is applicable for infants from 5 kg through adult patients who require invasive or non-invasive support via the following ventilatory modalities:

- Assist/Control and SIMV with either Volume, Pressure, or Pressure Regulated Volume Control (PRVC)
- CPAP with Pressure Support and CPAP / Pressure Support Volume Guaranteed [VG]
- Adaptive Bi-Level for either NIV or invasive ventilation and Adaptive Bi-Level Volume Guaranteed [VG]

The iVent101 ventilator is suitable for use in institution, home and portable settings

Technology: The iVent101 has been updated from the predicate version K092135. There have been no changes to the general intended use of the device to provide continuous or intermittent ventilator support or to the fundamental scientific technology. The indications for use was updated to include two additional ventilation modes CPAP/PSV Volume Guaranteed [VG] and Adaptive Bi-Level Volume Guaranteed [VG].

The software for the iVent101 in this submission has been updated to introduce minor software modifications and additional ventilation modes.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The iVent101 has been thoroughly tested through verification of Specifications and validation, including software validation. The following quality assurance measures were applied to the development of the system:

1. Risk Analysis
2. Requirements Reviews
3. Design Reviews
4. Testing on unit level (Module verification)
5. Integration testing (System verification)
6. Performance testing (Verification)
7. Safety testing (Verification)
8. Simulated use testing (Validation)

Summary of Clinical Tests:

The subject of this premarket submission, the iVent101, did not require clinical studies to support substantial equivalence.

Conclusion:

GE Healthcare, VersaMed Medical Systems considers the iVent101 to be as safe, as effective, and the performance to be substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Shlomi Deler
Regulatory Affairs Manager
VersaMed Medical Systems Limited
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Kadima
ISRAEL 60920

JUN 29 2012

Re: K112754
Trade/Device Name: iVent101
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK, NOU
Dated: May 4, 2012
Received: May 7, 2012

Dear Mr. Deler:

This letter corrects our substantially equivalent letter of June 15, 2012.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: iVent101

Indications for Use:

The iVent101 ventilator [with single or dual limb configuration] is intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. Specifically, the ventilator is applicable for infants from 5 kg through adult patients who require invasive or non-invasive support via the following ventilatory modalities:

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Prescription Use_xxx__ AND/OR Over-The-Counter Use_ _
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off)
ivision of Anesthesiology, General Hospital
nfection Control, Dental Devices

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